

# Alcide CORPORATION

8561 154th Avenue NE, Redmond, WA 98052 206-882-2555 Fax: 206-861-0173

Dr. R.L. Martin,  
Office of Premarket Approval,  
Center for Food Safety & Applied Nutrition,  
Food and Drug Administration,  
200 C Street, SW.,  
HFS-215  
Washington,  
D.C. 20204.

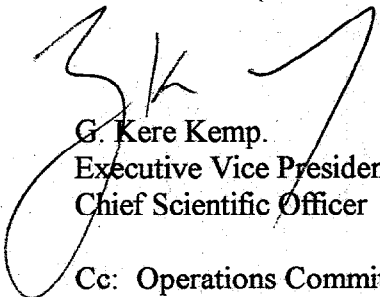
January 31, 2001

Dear Dr. Martin,

Re: Food Additive Petition 0A4724 – Acidified solutions of sodium chlorite for processing water applied to processed, comminuted or formed meat products.

As discussed and agreed with Ms. Glover Glew, I am enclosing three signed, revised copies of the Environmental Assessment for the above referenced petition, incorporating all of the revisions as recommended. Please advise if any additional information is required.

Yours sincerely,



G. Kere Kemp.  
Executive Vice President  
Chief Scientific Officer

Cc: Operations Committee

File: 750(b)

00F-1488

EA-1

# **§171.1(c)(H) ENVIRONMENTAL ASSESSMENT**

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## 4 DESCRIPTION OF THE PROPOSED ACTION

### 4.1 REQUESTED APPROVAL

Approval is requested for the use of the system comprised of acidified sodium chlorite (ASC) solutions for use as an antimicrobial agent to reduce pathogenic microorganisms (e.g., *Listeria monocytogenes*) prior to packaging on processed comminuted or formed meat products. These products include (as defined in *Sausage and Processed Meats Manufacturing*<sup>1</sup>):

- i) uncooked products in casings, such as **fresh sausage** and **uncooked smoked sausage**
- ii) cooked products, with or without casings, such as **cooked smoked sausage, other cooked sausage, and luncheon meats**

The petitioned additive was originally approved on April 23, 1996 and codified as 21CFR §173.325 (Alcide's FAP 4A4433) as an antimicrobial agent in the processing of poultry meat as a component of a carcass spray or dip solution prior to immersion in pre-chiller or chiller waters, or for direct application in pre-chiller or chiller water solutions. Further approvals for the additive have been granted in the intervening period. As of the date of submission of the current FAP, the approved applications for acidified sodium chlorite on poultry meat were most recently codified and/or listed in the Federal Register on March 28, 2000. A copy of this listing follows:

(b) (1) The additive is used as an antimicrobial agent in poultry processing water in accordance with current industry practice under the following conditions:

- (i) As a component of a carcass spray or dip solution prior to the immersion of the intact carcass in a prechiller or chiller tank;
- (ii) In a prechiller or chiller solution for application to the intact carcass;
- (iii) As a component of a spray or dip solution for application to poultry carcass parts; or

(iv) In a prechiller or chiller solution for application to poultry carcass parts.

(2) When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1200 parts per million (ppm), in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

(3) When used in a prechiller or chiller solution, the additive is used at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.8 to 3.2.

US Department of Agriculture (USDA) interim approval for the use of ASC solutions on Poultry Meat was also granted on January 7<sup>th</sup>, 1999 as a consequence of a petition submitted by Alcide Corporation to amend 9 CFR 381.147(f)(4). Final rule making to amend 9 CFR 381.147(f)(4) is in process at the time of writing of the current petition.

Acidified sodium chlorite solutions, of similar concentration ranges of chlorite and GRAS acid, have been approved as antimicrobial agents in the processing of red meat, red meat parts, and organs. As of the date of submission of the current FAP, the approved applications for acidified sodium chlorite on red meat, parts, and organs were most recently codified and/or listed in the Federal Register on March 28, 2000. A copy of this listing follows:

(c) The additive is used as an antimicrobial agent in accordance with current industry practice in the processing of red meat, red meat parts, and organs as a component of a spray or in the processing of red meat parts and organs as a component of a dip. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9.

US Department of Agriculture (USDA) approval for the use of ASC solutions on red meat products, including carcasses, parts, and organs was also granted on February 11, 2000.

In ASC solutions, there are two components that are used to create the antimicrobial effect; any GRAS acid and sodium chlorite. Sufficient acid is added to a 500 - 1,200 parts per million (ppm) sodium chlorite solution to reduce its pH to the 2.5 - 2.9 range. The resulting ASC solutions are then applied to the surfaces of the products, which are the subject of this petition as either a spray or a dip. In the former case, the liquid is dispensed from a spray apparatus in which either:

- i) Two streams of the chlorite and the acid solutions are mixed at, or immediately before the spray nozzle, or;
- ii) A single stream of ASC solution is directed to the spray nozzle from a pre-mixed solution. The latter may be prepared up to 8-hours prior to spraying, preferably in cold water, so long as the chlorite and acid levels have been analytically determined to be within acceptable levels.

When the antimicrobial solution is applied as a dip, the cooked products are immersed in the dip solution for a brief period of time, generally 10 to 30 seconds. Following both spray and dip application, it is not necessary to rinse the product prior to packaging. The decision with respect to the selection of a spray versus a dip as the procedure for applying an ASC solution to the cooked products is a function of: i) the conformation of the surface to be treated; ii) the practicality of system installation in, and conformance with, current plant operations.

- i) ASC is a contact antimicrobial system and therefore is dependent upon adequate exposure to and contact with the contaminated surfaces to be treated in order to ensure an effective and significant reduction in the microbial populations present. In those instances where the surfaces present large areas of crenulation, infolding or other such masking of contaminated areas, then an immersion process may prove to be overall

more effective in ensuring complete coverage and contact of all surfaces with ASC. In contrast, where the surfaces to be treated are relatively smooth and even, a spray application of ASC will ensure the necessary surface coverage and contact to provide significant microbial reduction.

- ii) In many processing plants today, systems are already in place for the application of water and in some instances also antimicrobial substances, to cooked products. These are typically either short term immersion dip systems in which product is passed through a liquid filled container or spray systems in which the spray coverage of the cooked product is achieved while the latter travels through an enclosure on suitable conveyors, trays etc. Modification of such systems to accommodate an ASC spray or immersion dip can often be readily achieved with minimal inconvenience or modification to plant systems, layout or operation.

## 4.2 NEED FOR THE ACTION

Millions of Americans become ill each year from something they eat. While diagnostic and surveillance methods for food borne illness have improved dramatically in recent years, the exact number of cases can still only be approximated, by government officials. As a result we must rely heavily on estimates when attempting to quantify the problem. As an example, the Centers for Disease Control and Prevention estimates that while deaths due to food poisoning have dropped from 9,000 to 5,000 per year, the actual number of illness' reported has risen to approximately 76 million per year. Much of this increase is attributed to better surveillance and more accurate diagnosis. 30% of the reported food poisonings are also now known to be bacterial in origin, arising mainly from infections due to *Campylobacter jejuni*, *Salmonella spp.* and *Shigella spp.*

There is a strong need for good hygienic practices during preparation and/or after cooking of the products which are the subject of this petition, in order to ensure the unbroken microbiological safety and quality of these foods. Of particular importance are pathogenic organisms such as *Listeria monocytogenes* that can contaminate the product during the cooling and packaging of the products. Even if proper temperatures are achieved during the cooking of the finished product to destroy the pathogens, or the components of the product were decontaminated with the previously approved system of ASC solutions, they may become recontaminated prior to packaging. The Centers for Disease Control and Prevention calculates that *L. monocytogenes* alone infects 1,850 Americans a year through contaminated ready-to-eat meats, cheeses, produce and other sources. Additionally, *L. mynocytoenes* accounted for nearly half of the deaths caused by food borne pathogens, with an estimated 425 deaths nationwide. Pregnant women and their unborn or newborn children are at increased risk, as well as persons with weakened immune systems.

*L. monocytogenes* is often found in the intestines of healthy animals, including humans, and in soil, water, and vegetation. It is particularly difficult to eliminate in processing plants, as it thrives in cool, moist environments on the surfaces of equipment, floors, walls, and in floor drains. Because of its pervasiveness throughout the plant, it is difficult to completely eliminate *Listeria monocytogenes* from the cooling and packaging areas of the products which are the subject of this petition. Furthermore, *L. monocytogenes* is not killed by freezing and flourishes during refrigerated storage.

It is the position of the Alcide Corporation that the ASC solutions which are the subject of this Food Additive Petition, and which have already been approved by the FDA for use in both poultry and red meat carcass processing, can play a major role in upgrading the microbial quality of the products which are the subject of this petition. Particularly, pre-cooked ready-to-eat foods, by their very nature, are



assumed by the consumer to be safe to eat without further preparation precautions.

### 4.3 LOCATIONS WHERE PRODUCTS WILL BE PRODUCED

There are two components to the acidified chlorite solutions being proposed for Secondary Direct Food Additive Status, the sodium chlorite and an acid needed to achieve the desired solution pH. The acid can be any one of a variety of FDA-approved generally-recognized-as-safe (GRAS) acids, including phosphoric, sulfuric, malic, acetic and citric. These are all materials of very high volume usage, and of many current diverse applications. The projected volumes of use as an activator of sodium chlorite are much below a fractional percentage of the other applications. Thus the sites of production of these different acids are not considered relevant to this environmental assessment.

Sodium chlorite is currently being used as a chlorine dioxide ( $\text{ClO}_2$ ) source in water treatment, as well as an industrial bleaching agent in a number of industries (primarily pulp and paper), in cleaning applications for the electronics industry, as a biocide in the food processing industry, and in various applications in the oil industry. On April 23, 1996 the U.S. FDA first approved the use of sodium chlorite as a component of ASC solutions for microbial reduction in poultry processing. Thereafter, as a result of similar approval actions the FDA has also allowed for the use of ASC solutions; i) pre-chill in red meat carcass sprays or dips; ii) post-chill in red meat, red meat parts and organ sprays or dips; iii) pre-process on Raw Agricultural Commodities; iv) in process waters on sea food.

The size of the North American market in 1992 was estimated at 18 million lb. per year, and with a demand for chlorite growing (at the expense of chlorine) at a rate of 8% to 9% per year, reached approximately 25 million lb. per year by 1996<sup>(a)</sup>. The major producer of sodium chlorite in the U.S. is Vulcan Chemicals, of

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(a) Resurgence in Demand Reviving Market for Sodium Chlorite", in Chemical and Engineering News, p. 11,12 March 22, 1993.

Birmingham, Alabama. Vulcan's facility in Wichita, Kansas produces 18 million lb. per year. Sterling Chemicals, of Houston, Texas produces 8 million lb. per year sodium chlorite at its manufacturing plant in Buckingham, Quebec. Foreign production sites for sodium chlorite, which may be accessed if quality and economics are appropriate, include France's Atochem, S.A., the world's largest producer, and Energia Industrias Aragonesas, Madrid, Spain.

#### 4.4 LOCATIONS WHERE THE PRODUCTS WILL BE USED

Once the pending Food Additive Petition is accepted as a regulation, the acidified chlorite antimicrobial will become available to all central processing plants in the United States as well as local supermarkets and butchers. Generally the central processing plants are located in the same geographic areas as the abattoirs, and further processing occurs at the central processing plants or nearby facilities. Of the top 25 meat and poultry producers in North America, the following 14 U.S. companies are also producers of processed meats such as those which are the subject of this petition. The ranking within the top 25, the names, and base of operation are as listed:

##### Producers of Fresh, Cooked, and Traditional Sausage, and Luncheon Meats<sup>2</sup>

- |    |                         |                        |
|----|-------------------------|------------------------|
| 1) | ConAgra, Inc.           | Omaha, Nebraska        |
| 2) | IBP, Inc.               | Dakota City, Nebraska  |
| 3) | Cargill Meat Sector     | Minneapolis, Minnesota |
| 5) | Sara Lee Packaged Meats | Chicago, Illinois      |
| 6) | Smithfield Foods, Inc.  | Smithfield, Virginia   |
| 7) | Farmland Foods, Inc.    | Kansas City, Missouri  |
| 8) | Hormel Foods            | Austin, Minnesota      |

9)	Oscar Meyer Foods	Madison, Wisconsin
11)	Perdue Farms, Inc.	Salisbury, Maryland
17)	WLR Foods, Inc.	Broadway, Virginia
18)	Foster Poultry Farms, Inc.	Livingston, CA
19)	Thorn Apple Valley, Inc.	Southfield, Mississippi
21)	American Foods Group	Green Bay, Wisconsin
22)	Colorado Boxed Beef Co.	Winter Haven, Florida

As Kansas, Texas, Colorado, Iowa, Pennsylvania and Washington are among the top ten red meat producers according to the American Meat Institute, additional further processing facilities are located in these states. As expected, the majority of facilities are in the Midwest, where the beef and pork industry is concentrated with some additional plants near poultry producing areas. Frozen meats are also shipped to other locations for further processing, however, and therefore additional processing facilities of varying sizes are located throughout the United States.

It is difficult to obtain an estimate of the sausage and luncheon meats that are produced locally, but it appears from the above information that the predominance of comminuted meat production will focus in the central U.S. states, with local production accounting for somewhat less usage in the eastern and far-western states. The projected usage of the petitioned ASC solutions will generally correspond in volume to the production site locations described above.

## **5.0 IDENTIFICATION OF CHEMICAL SUBSTANCES THAT ARE SUBJECT OF THE PROPOSED ACTION**

### **5.1 CHEMICAL NAMES AND PHYSICAL PROPERTIES**

#### **5.1.1 Sodium Chlorite**

CAS Reg. No.:	7758-19-2
Color (25% -37% Solution):	Colorless to light green
Specific Gravity:	1.20-1.25
Viscosity (@25°C):	1-2 cps
pH:	>12

#### **5.1.2 Acidifiers (GRAS)**

##### **Phosphoric Acid**

CAS Reg. No.: 7664-38-2  
Conforms with 21CFR §182.1073 as a Multiple Purpose GRAS Food  
Substance

##### **Citric Acid**

CAS Reg. No.: 77-92-9 (anhydrous)  
5949-29-1 (monohydrate)  
Conforms with 21CFR §182.1033 as a Multiple Purpose GRAS Food  
Substance

### **Hydrochloric Acid**

CAS Reg. No.: 7647-01-0

Conforms with 21CFR §182.1057 as Multiple Purpose GRAS Food Substance

### **Malic Acid**

CAS Reg. No.: 617-48-1 DL mixture

97-67-6 L isomer

Conforms with 21CFR §184.1069 as a Specific Substance Affirmed as GRAS, with respect to the following ¶'s,

- (a) description
- (b) specifications
- (c) use as pH control agent
- (d) maximum use level

### **Sulfuric Acid**

CAS Reg. No.: 7664-93-9

Conforms with 21CFR §184.1095 as a Specific Substance Affirmed as GRAS, with respect to the following ¶'s,

- (a) description
- (b) specifications
- (c) use as pH control agent
- (d) maximum use level

## Acetic Acid

CAS Reg. No.: 64-19-7

Conforms with 21CFR §184.1005 as a Specific Substance Affirmed as GRAS, with respect to the following ¶s,

- (a) description
- (b) specifications
- (c) use as a pH control agent
- (d) maximum use level

The subject of this food additive petition (FAP) is the system comprised of acidified aqueous sodium chlorite solutions for use as an antimicrobial agent to reduce pathogenic microorganisms on organs and red meat cut surfaces, particularly those subject to subsequent comminution or grinding into such items as hamburger patties, ground beef or sausage. The composition and concentration of the system depends on the mode, site of application of the antimicrobial solution (*e.g.*, large processing facility, supermarket) and quantity of meat being processed.

## 5.2 MODE OF ACTION OF THE GERMICIDAL SYSTEM

Acidified Sodium Chlorite (ACS) chemistry is principally the chemistry of chlorous acid ( $\text{HClO}_2$ ; CAS No. 13898-47-0), a metastable oxychlorine species which decomposes to form chlorate ion, chlorine dioxide, and chloride ion<sup>3</sup>. To better understand chlorous acid chemistry, a brief overview of the chemistry of various oxychlorine species will be given.

As illustrated in Table 1, chlorine can exhibit oxidation states from -1 to +7.

As a consequence, its chemistry is varied and complex.

**Table 1. Oxidation States of Chlorine**

$\text{ClO}_4^-$	+7	Perchlorate ion
$\text{ClO}_3^-$	+5	Chlorate ion
$\text{ClO}_2$	+4	Chlorine
$\text{ClO}_2^-$	+3	Chlorite ion
$\text{ClO}^-$ or $\text{OCl}^-$	+1	Hypochlorite
$\text{Cl}_2$	0	Chlorine
$\text{Cl}^-$	-1	Chloride ion

Oxychlorine species are important as oxidants in a number of applications. The strength of an oxidant is measured by its oxidation strength, or oxidation potential. Table 2 lists some of the more common oxidants, the associated oxidation reaction, the oxidation strength (measured in volts), and the oxidation capacity (the number of electrons accepted by the oxidant). The chlorous acid ( $\text{HClO}_2$ ) reaction, with its 1.57 V oxidation strength and 4-electron oxidation capacity, ranks just below ozone and the hydroxyl-radical generation reaction of hydrogen peroxide.

**Table 2. Common Oxidation Reactions**

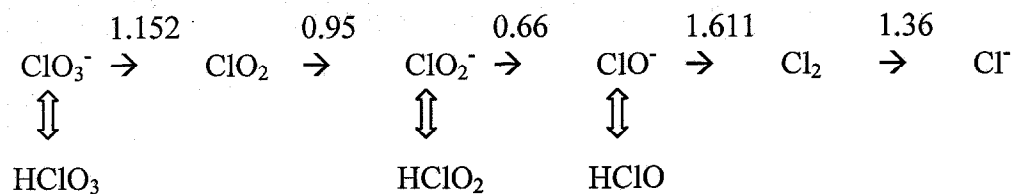
Oxidant Reaction	Common Name	Oxidation Capacity	Oxidation Strength (V)
$\text{O}_3 + \text{H}_2\text{O} + 2 \text{e}^- \rightarrow \text{O}_2 + \text{OH}^-$	Ozone	$2\text{e}^-$	2.07
$\text{H}_2\text{O}_2 + 2\text{e}^- \rightarrow 2 \text{OH}^-$	Hydrogen Peroxide	$2\text{e}^-$	1.78
$\text{HClO}_2 + 3 \text{H}^+ + 4 \text{e}^- \rightarrow \text{Cl}^- + 2 \text{H}_2\text{O}$	Chlorous Acid (Acidified Sodium Chlorite)	$4\text{e}^-$	1.57
$\text{ClO}_2 (\text{v}) + \text{e}^- \rightarrow \text{ClO}_2^-$	Chlorine Dioxide (Vapor Phase)	$1\text{e}^-$	1.56
$\text{HOCl} + \text{H}^+ + 2 \text{e}^- \rightarrow \text{Cl}^- + \text{H}_2\text{O}$	Hypochlorous acid	$2\text{e}^-$	1.49
$\text{HOBr} + \text{H}^+ + 2 \text{e}^- \rightarrow \text{Br}^- + \text{H}_2\text{O}$	Hypobromous acid	$2\text{e}^-$	1.33
$\text{ClO}_2 + 4 \text{H}^+ + 5 \text{e}^- \rightarrow \text{Cl}^- + 2 \text{H}_2\text{O}$	Acidified Chlorine Dioxide	$5\text{e}^-$	1.51
$\text{ClO}_2 (\text{aq}) + \text{e}^- \rightarrow \text{ClO}_2^-$	Chlorine Dioxide (Aqueous Phase)	$1\text{e}^-$	0.95
$\text{ClO}_2^- + 2\text{H}_2\text{O} + 4\text{e}^- \rightarrow \text{Cl}^- + 4 \text{OH}^-$	Chlorite	$4\text{e}^-$	0.78



As mentioned before, oxychlorine chemistry is varied and complex. Listed below are oxidation half-cell reactions and their corresponding oxidation potentials for several additional reactions of oxychlorine species given by Gordon *et al.*<sup>4</sup>, in the AWWA publication, *Disinfectant Residual Measurement Methods*:

$\text{HClO}_2 + 3 \text{H}^+ + 4 \text{e}^- \rightarrow \text{Cl}^- + 2 \text{H}_2\text{O}$	1.57 V
$\text{HClO}_2 + 2 \text{H}^+ + 2 \text{e}^- \rightarrow \text{HClO} + \text{H}_2\text{O}$	1.645V
$\text{HOCl} + \text{H}^+ + \text{e}^- \rightarrow \frac{1}{2} \text{Cl}_2 + \text{H}_2\text{O}$	1.611 V
$\text{HOCl} + \text{H}^+ + 2 \text{e}^- \rightarrow \text{Cl}^- + \text{H}_2\text{O}$	1.49 V
$\text{ClO}_3^- + 6 \text{H}^+ + 5 \text{e}^- \rightarrow \frac{1}{2} \text{Cl}_2 + 3 \text{H}_2\text{O}$	1.47 V
$\text{ClO}_3^- + 6 \text{H}^+ + 6 \text{e}^- \rightarrow \text{Cl}^- + 3 \text{H}_2\text{O}$	1.451 V
$\text{Cl}_2 + 2 \text{e}^- \rightarrow 2 \text{Cl}^-$	1.36 V
$\text{ClO}_2 + \text{H}^+ + \text{e}^- \rightarrow \text{HClO}_2$	1.25 V
$\text{ClO}_3^- + 3 \text{H}^+ + 2 \text{e}^- \rightarrow \text{HClO}_2 + \text{H}_2\text{O}$	1.214 V
$\text{ClO}_3^- + 2 \text{H}^+ + \text{e}^- \rightarrow \text{ClO}_2 + \text{H}_2\text{O}$	1.152 V
$\text{ClO}_2 + \text{e}^- \rightarrow \text{ClO}_2^-$	0.95 V
$\text{ClO}^- + \text{H}_2\text{O} + 2 \text{e}^- \rightarrow \text{Cl}^- + 2 \text{OH}^-$	0.81 V
$\text{ClO}_2^- + 2 \text{H}_2\text{O} + 4 \text{e}^- \rightarrow \text{Cl}^- + 4 \text{OH}^-$	0.76 V
$\text{ClO}_2^- + \text{H}_2\text{O} + 2 \text{e}^- \rightarrow \text{ClO}^- + 2 \text{OH}^-$	0.66 V
$\text{ClO}_3^- + 3 \text{H}_2\text{O} + 6 \text{e}^- \rightarrow \text{Cl}^- + 6 \text{OH}^-$	0.62 V

The oxidation potential diagram given below shows that chlorous acid is unstable with respect to disproportionation, i.e. chlorous acid is a metastable species.



Numerous researchers have determined that the decomposition reaction of chlorous acid is approximately second order with respect to chlorous acid<sup>5,6,7,8</sup>. At pH values above 2.0 where  $[\text{ClO}_2^-] > [\text{HClO}_2]$ , the rate law can be written as follows:

$$\frac{-d[\text{HClO}_2]}{dt} = k [\text{HClO}_2]^2$$

(where  $k = 0.023 \text{ M}^{-1} \text{ sec}^{-1}$  at  $25^\circ\text{C}$ )<sup>9</sup>

It is known that chloride ion accelerates the decomposition of chlorous acid and also alters the stoichiometry, Hong<sup>10,11</sup> developed the following empirical rate expression for the decomposition of chlorous acid, with the effect of chloride taken into account;

$$\frac{d[\text{ClO}_2]}{dt} = (m + nx) \left( 1 - \frac{x}{p + qx} \right)$$

$$\text{where } m = 2\{k_1[\text{HClO}_2]^2 + k_2 [\text{ClO}_2^-][\text{HClO}_2]\}$$

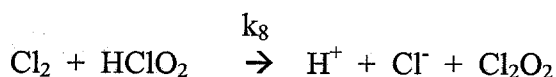
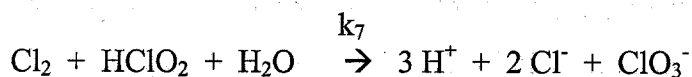
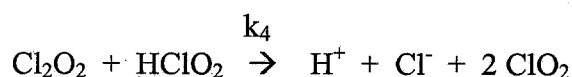
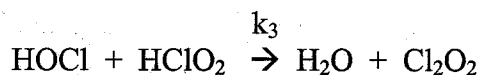
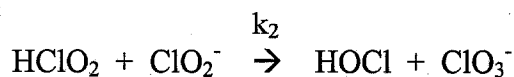
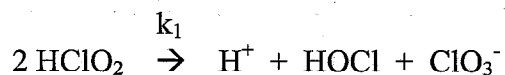
$$n = 4 k_5 [\text{H}^+][\text{HClO}_2]$$

$$p = \frac{k_3(k_7 + k_8)[\text{HClO}_2]}{k_6 k_7 [\text{H}^+]}$$

$$q = \frac{k_7 + k_8}{k_7}$$

$$x = [\text{Cl}^-]$$

(Where the various rate constants refer to the following set of reactions:)



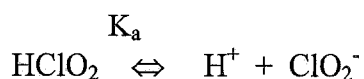
In the absence of chloride, only the first four reactions need be considered. Doing this, Hong gives the following reaction equation, valid over the pH range of 0 to 3, for the initial rate law for the formation of chlorine dioxide:

$$\frac{d[\text{ClO}_2]}{dt} = k [\text{HClO}_2]^2 + k' [\text{HClO}_2][\text{ClO}_2^-]$$

The rate of formation of chlorine dioxide given above can be related approximately to the disappearance of chlorous acid by the following relation<sup>7</sup>:

$$-d[\text{HClO}_2]/4 = d[\text{ClO}_2]/2$$

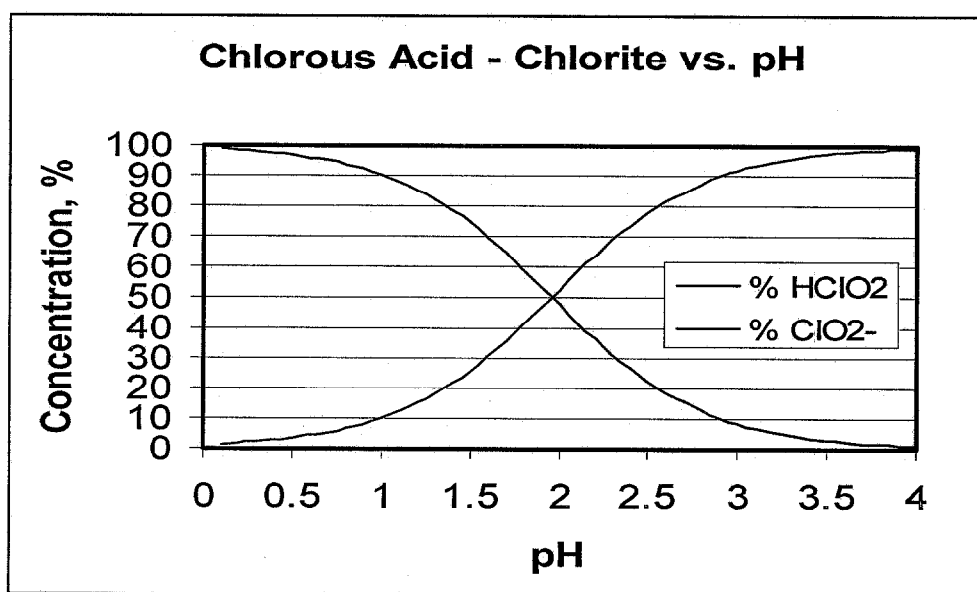
In aqueous solution, chlorous acid, a relatively weak acid, dissociates as follows:



Where  $K_a$ , the acid dissociation constant, is  $1.01 \times 10^{-2}$  at  $23^\circ\text{C}$ <sup>12</sup>. In terms of the acid dissociation constant (ionization constant) and the hydrogen ion concentration of the solution ( $=10^{-\text{pH}}$ ), the chlorous acid concentration can be found from the total titratable chlorite concentration as follows:

$$\% \text{HClO}_2 = \frac{1}{1 + (1.1 \times 10^{-2})/[\text{H}^+]} \times 100\%$$

The following is a graph of this relationship.



The optimal parameters for application of the Acidified Sodium Chlorite process as a short-term antimicrobial intervention have therefore been determined to be:

- i) A pH range of approximately 2.5 to 2.9;
- ii) A sodium chlorite concentration ranging from 500 ppm to 1200 ppm.

## 6.0 INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT

### 6.1 PRODUCTION RELEASES

As noted in Section 4, the ASC solution will be produced on site immediately before application in the processing facility, be it a major operation, a contract operation for a specific chain, or ultimately even a supermarket facility. The solution mixing will take place through the confluence of the separate acid activator and sodium chlorite solutions at some point prior to the final applicator nozzles. The acid and sodium chlorite solutions will be prepared in ambient temperature tap water. During the brief time (no greater than 2 – 3 minutes) that will elapse between the creation/activation of the ASC solution and its final delivery to the surface to be treated, the levels of dissolved chlorine dioxide that are typically generated within the ASC solution will not exceed *ca.* 1 – 2 mg/liter (1 – 2 ppm).

In larger operations, it is anticipated that a spray treatment is most likely to be the primary mode of application to products which are the subject of this petition, in essentially the same manner as is currently commercially utilized for the pre-chill ASC treatment of whole poultry carcasses or carcass parts; i.e. they will pass through a semi-enclosed and baffled spray enclosure. The spray will be applied via pressurized spray nozzles, for varying exposure times up to about 30 seconds before the product exits the enclosure. In order to minimize the potential for possible off-gassing into the immediate worker environment, the semi-enclosed spray enclosure will be negatively pressurized via an aspirating air hose venting to the outside of the building. This will ensure the removal of excess gaseous materials, while a dedicated drainpipe will route excess fluids to an enclosed drain for removal with other plant wastes. Short term exposure, immersion dip processes may also be developed for the products that are the subject of this petition and, as for the spray treatments, such systems would also be semi-enclosed and negatively pressurized via an

aspirating air hose venting to the outside of the building.

In smaller operations where the application of product is expected to typically be limited to infrequent and/or small batch application using hand-held "on/off-type" applicators, the volume of product use and therefore the potential for off-gassing and worker environment exposure is significantly reduced compared to the larger commercial systems. As a result, no special precautions other than the inclusion of label precautionary statements regarding handling and use of the material are therefore anticipated.

#### **6.1.a. THEORETICAL WORST-CASE PRODUCTION RELEASES**

While chlorine dioxide has a minimum tendency to form in ASC solutions when, the chlorite and acid are initially combined immediately prior to spraying (typically measured as  $< 1 - 2$  mg/liter dissolved in solution), it may exhibit an increasing tendency to form as the applied solution concentrates during the evaporative process. Thus, in a typical situation, the potential for chlorine dioxide entry into the air of the workplace would be expected to derive primarily from this evaporative source, more so than from that which is retained in solution. Chlorine dioxide also has a significant tendency to react with, and be degraded by soluble organic matter (such as blood proteins) to chlorite and ultimately chloride. It is therefore expected that a major portion of both the initially projected chlorine dioxide maximum of  $1 - 2$  mg/liter in solution and any quantity formed upon subsequent solution evaporation will be reduced to a non-volatile, chlorine-containing ion that will be removed in the organic matter laden waters of the processing plant.

It is further expected that the degree of ASC evaporation of, and concentration-induced creation of chlorine dioxide during the treatment's residence time on the products will be low. This is particularly true because the high humidity conditions prevailing in the cabinet will tend to suppress evaporation, and if a dip application is used, no evaporation will occur during application. Thus the projected 1-mg/liter level of chlorine dioxide is expected

to correspond to the maximum amount from both initial and evaporative sources.

To put this into perspective, assume that an ASC spray operation uses 30 mL of ASC solution per hot dog applied in a spray cabinet measuring 4 M<sup>3</sup> (1M in height and 2M in width and length) over the course of 30 seconds. 1,000 pounds of hot dogs (10,000 hot dogs) treated would correspond to 300 liters of ASC solution sprayed over a period of 4.8 minutes.<sup>(b)</sup> Therefore, in a "worst-case" scenario if all of the dissolved chlorine dioxide (at a concentration of 2-mg/liter) were to be released into the environment, this would release 600 mg in 4.8 minutes or 125 mg/min. Assuming a static air environment, with no venting or circulation of the air in the vicinity of the spray operation, the dispersal of 125 mg into only 4 M<sup>3</sup> of air would rapidly raise its concentration above the OSHA 8-hour TLV of 0.3 mg/M<sup>3</sup>, leading to unsafe conditions within the enclosure and in the immediate external environs.

#### 6.1.b ACTUAL PRODUCTION RELEASES

Air quality testing in the immediate area around commercial spray enclosures installed into poultry plants in the US shows that chlorine dioxide is generally undetectable (Appendix 1). Additionally, air quality testing of the air exhaust from these same commercial systems shows extremely low levels of chlorine dioxide present, further supporting the fact that the majority of the material that is in solution remains so and is ultimately disposed of in the liquid waste stream.

In an immersion or dipping operation there is not expected to be any change, certainly no increase to the potential for air dispersal of either the ASC solution or of any dissolved chlorine dioxide, when compared to that of a spray operation. As with the SANOVA<sup>®</sup> commercial spray systems, the environs surrounding an immersion or dipping operation will be controlled with appropriate enclosures, containment of liquid wastes and positive pressure

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(b) Estimating that a large plant would produce 1 million pounds per week in an 80-hour work week; the

air venting.

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rate of production would be 12,500 lb/hour or 1,000 lb/ 10,000 hotdogs in 4.8minutes.



## 6.2 USE RELEASES

### 6.2.1 ESTIMATES OF RAW MATERIAL VOLUME

#### 6.2.1.a INTRODUCTION

Data on the exact amount of red meat and poultry that is further processed into products which are the subject of this petition is difficult to obtain in the US since actual industry practices vary widely due to market demand and changes in the market interest. According to the American Meat Institute (AMI), the average American consumed 212.2 lb of meat and poultry in 1994, and this includes 34.2 lb of processed products.<sup>13</sup> Hot dog production is well documented, but the product breakdown of the remaining sectors of the processed product industry is not. Hot dogs comprise nearly 20 percent of the processed meat market, with production estimated to be approximately two billion pounds annually.

One local small processor provided the following product breakdown during the previous year, showing some of the variation that occurs with seasonal demands:

<u>Month</u>	<u>Product type</u>	<u>lb produced</u>	<u>% of total production</u>
February	Sausage (cooked and raw)	27,000	25.7
	Ham	20,000	19.0
	Bacon	58,000	55.2
		105,000	
August	Sausage (cooked and raw)	42,000	32.1
	Ham	21,000	16.0
	Bacon	68,000	51.9
	Total	131,000	

This is similar to the estimate by the *Meat Marketing and Technology Magazine*, that 25% of the total processed meat market each year is sausage. However, this processor only uses pork, and therefore does not produce lunchmeats, etc. from poultry. For the purposes of use release estimates, perhaps another 25% of the average American processed meat consumption can be attributed to lunchmeats, and the remaining 50% to ham, bacon, and other processed meats that are not within the scope of this petition.

These production estimates along with an estimated application rate of 10.0 fl oz / Kg (0.136 L / lb) of processed meat will be applied to obtain theoretical estimates of the potential usage rates for sodium chlorite.

### **“Volume Applied Calculation.**

The calculation of an average ASC application rate for a typical cooked product (frankfurter) was based on Alcide Corporation's accumulated experiences to date in the application of ASC to beef carcasses. This application was chosen because the typical post-slaughter beef carcass surface has been found to be relatively pH stable and therefore to have minimal impact on the ASC chemistry – as has also been found to be the case with a typical frankfurter surface.

The average surface area of an adult cattle carcass side is 39,100 cm<sup>2</sup> while the average ASC application rate per carcass side ranges between 1 to 2 gallons (3.785 to 7.570 liters). The average application rate per unit of surface area is therefore:

0.0968 ml/cm<sup>2</sup> - at an application rate of 1 gallon per side

0.1935 ml/ cm<sup>2</sup> - at an application rate of 2 gallons per side

The surface area of an average frankfurter is 91.1 cm<sup>2</sup> while the average frankfurter

weight is 0.04 kg (0.1 lb). Thus, using the typical beef carcass treatment parameters as the most likely upper and lower limits for the potential volume to be applied to frankfurters, the average application rates calculate as follows:

At a rate of 0.0968 ml/cm<sup>2</sup> an average frankfurter would require:

$$0.0968 \times 91.1 = 8.8185 \text{ ml}$$

$$8.8185 \text{ ml} / 0.04 \text{ kg} = 194.2 \text{ ml} / \text{kg}$$

194.2 ml / kg is equivalent to **6.85 fl oz / kg**

At a rate of 0.1935 ml/cm<sup>2</sup> an average frankfurter would require:

$$0.1935 \times 91.1 = 17.6279 \text{ ml}$$

$$17.6279 \text{ ml} / 0.04 \text{ kg} = 388.3 \text{ ml} / \text{kg}$$

388.3 ml / kg is equivalent to **13.69 fl oz / kg**

Until such time as a commercial application system has been developed and installed, considerable uncertainty will remain in establishing the final application rate for use on frankfurters or other cooked products. In the absence of any additional data the approximate mid-point of **10.0 fl oz / kg** was therefore selected for all calculations in this Environmental Assessment relating to estimates of raw material volume use.

### 6.2.1.b SODIUM CHLORITE ESTIMATES

Based on the estimate that 50% of processed meat products consist of the product categories which are the subject of this petition, as described above, with an average consumption of 34.1 lb of processed meats total per person and a total U.S. population of 300 million, an estimate is obtained that 5,115 M lb of processed meats could be treated with ASC annually. Assuming a "worst-case" scenario where all of this product is treated with ASC, the following estimate of sodium chlorite usage can be derived:

Total meat processed = 5,115 million lb

Treatment rate = 0.136 L/lb

Treatment volume = 0.136 L/lb x 5,115 million lb = 696 million L

Sodium chlorite use rate = 1.2 g/L

Total sodium chlorite use = 696 million L x 1.2 g/L x 1 Kg/1000 g = 0.835 million Kg

Therefore, in this worst-case scenario assuming that all processed products which are the subject of this petition were to receive exposure to an ASC treatment, the total sodium chlorite usage per annum is estimated to be 0.835 million Kg or 7.3% of the total sodium chlorite market in the US (estimated at 11.35 million Kg in 1996). Clearly this number is highly inflated and does not reflect a realistic picture of the industry's likely adoption of the ASC technology, or their likely use of alternative intervention technologies and the impact thereof. A more likely scenario is that ASC solutions might be expected to achieve a 20% share of the intervention technology market that is finally adopted by the processed meat industry. Under this scenario, the projected total sodium chlorite usage per annum would be 0.167 million Kg. This equates to approximately 1.5% of the estimated current market for this material in the US.

## **6.2.2 WATER AND AIR RELEASE**

### **6.2.2.a INTRODUCTION**

The components of the ASC solutions are the GRAS acid, of high purity, and the sodium chlorite (of a technical grade), which has sodium chloride and sodium chlorate as impurities. Upon acidification the chlorite, through chlorous acid, can be expected to minimally transform to chlorine dioxide and to chlorate. At the level of use of these components, and the minimum standing time for the mixed ASC solution, the amount of chlorine dioxide that is dissolved in solution will not exceed *ca.* 1 –2 mg/liter. Being a highly reactive compound, this chlorine dioxide will quickly be reduced (by reaction with organic matter and with microorganisms on the product surfaces) to even smaller quantities of chlorite and chloride ions. An even lower amount of chlorate will also be formed in this process by a separate pathway involving disproportionation of the chlorine dioxide.

As shown from plant data in previous Section 6.1, the air releases of chlorine dioxide are negligible. Of greater possible concern are the relatively higher levels of sodium chlorite, i.e. 1200 ppm as a maximum, of which the chlorite ion represents 895 ppm. In the processed meat production industry, further processing into cooked, ready-to-eat products or fresh sausage may occur either as a secondary component of the slaughter operation in the same facility or in a separate, dedicated further processing facility, which acts as a central accumulation point for a number of slaughter operations.

### **6.2.2.b CHLORITE/CHLORATE/CHLORINE DIOXIDE WATER RELEASES - LARGER FACILITIES**

A "worst-case" estimate of the concentration of chlorite ion that might be discharged to Publicly Owned Treatment Works (POTWs), from ASC treatment of products, which are the subject of this petition, can be approximated from the following assumptions:

- ASC product will typically be applied prior to the final packaging step at the rate of 10 oz/1 kg = 300 mL/Kg = 0.3 L/Kg..
- At the maximum dose rate (1200 ppm), the amount of chlorite ion applied = 895 mg/L.  
 $\therefore$  The amount of chlorite applied = 269 mg/Kg treated.
- Assuming 10% of the chlorite is consumed in reaction on the product surface, the residual chlorite entering the waste stream = 242 mg/Kg treated.

Water usage figures were obtained from a small local processor (production figures were given in section 6.2.1.a above). Water usage figures were not available from large processors. From this facility, the water usage rate per Kg of products which are the subject of this petition are estimated as follows:

- During a six-week period in the spring, the total water usage for the facility was 395 units.
- 1 unit = 100 ft<sup>3</sup> = 100 x 28.32 L/ft<sup>3</sup>. Therefore the average water usage/ week was (395 units x 100 ft<sup>3</sup> x 28.32 L/ft<sup>3</sup>) / 6 weeks = 186,440 L/week.
- Using the total production numbers for February and August from section 6.2.1.a, the weekly average production rate is estimated to be 27,460 lb or 12,457 Kg.<sup>(c)</sup>
- If 50% of the total production was products which are the subject of this petition, this would be estimated at 0.5 x 12,457 Kg = 6228 Kg/ week.  
 $\therefore$  The water usage/Kg of products of interest is estimated as  
 (186,440 L/week)/(6228 Kg/week) = 29.9 L/Kg product.  
 $\therefore$  The amount chlorite ion that may possibly enter the waste stream from use on the products which are the subject of this petition is estimated as

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(c) 105,000 lb total in February, with 4.14 weeks; average = 25,345 lb/week. 131,000 lb total in August, with 4.43 weeks; average = 29,581 lb/week. Estimated average weekly production is therefore 27,463 lb.

$$242 \text{ mg}/29.9 \text{ L} = 8.1 \text{ mg/L} = 8.1 \text{ ppm}.$$

∴

For sodium chlorate, a worst-case estimate of the amount, which may be present, can be obtained from the following.

- Technical grade sodium chlorite, contains *ca.* 80%; pure material, and has no more than 4% sodium chlorate.

∴ At least initially, the ratio of chlorite to chlorate ion is  $\geq 20:1$ .

The levels of dissolved chlorine dioxide that are typically generated within the ASC solution will not exceed 2 ppm as stated in section 6.1. Therefore the level of chlorine dioxide in the plant effluent can be estimated as

$$(\leq 2 \text{ mg/L} \times 0.3 \text{ L/Kg})/29.9 \text{ L/Kg} = \leq 0.02 \text{ ppm}$$

Chloride ion is of no consequence, it being a small fraction (*ca.* 0.1) of the original chlorite, and a larger molar fraction (*ca.*  $\frac{1}{2}$ ) of the reacted chlorite on a weight basis. Chloride is also naturally present in such large quantities that any incremental amount arising from chlorite degradation is inconsequential.

Thus, estimates of the worst-case levels of chlorite, chlorate and chlorine dioxide exiting in the effluent from a large-scale processor's use of ASC, based on the figures shown in the previous sections, are:

chlorite	8.1 ppm
chlorate	$\leq 0.5$ ppm
chlorine dioxide	$\leq 0.02$ ppm

### 6.2.2.c ACID IN WATER RELEASES – LARGER FACILITIES

With respect to the GRAS acids the following are representative of the levels required (buffering included) to acidify sodium chlorite to the petitioned pH range of 2.5 - 2.9:

sulfuric acid	≤0.005% (≤50 ppm)
phosphoric acid	0.01 - 0.02% (100 - 200 ppm)
citric acid	0.6 – 0.9%

These levels are clearly quite low, and like sodium chlorite, will be similarly diluted further by other water sources contributing to the facilities' effluents. Using the same assumptions as for chlorite<sup>(d)</sup>, the approximate maximum calculated sulfuric, phosphoric and citric acid levels, which might exit from a processing facility, would be:

sulfuric acid	≤0.45 ppm
phosphoric acid	1.8 ppm
citric acid	81.3 ppm

### 6.2.2.d IMPACT OF WATER RELEASES – LARGER FACILITIES

The contribution of industrial discharges to POTWs is further diluted by discharges from non-industrial sources. An approximation of the further dilution by these other sources can be made from information made available in an EPA- sponsored study by Consulting Engineers<sup>14</sup> of discharge sources which have a negative impact on the operation of POTWs. The POTWs studied included a representative cross-section of U.S. municipal treatment facilities serving industrial and non-commercial dischargers. In the twenty-nine case study

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(d) Application rate = 0.3 L/Kg, 10% of acid consumed in reaction, and average 29.9 L/Kg waste-water usage.



reports provided in the survey, 26.3% of the influent wastewater to these facilities derived from industrial sources.

A single industrial discharge source to a particular POTW, such as a processed products facility, can be conservatively estimated to represent an upper limit of 50% of the total industrial discharge to a single POTW. Thus a water flow percentage contributed by a single processor to a POTW is 26.3% x 50%, or 13.2% of the total water processed. On that basis the approximate maximum calculated chlorite, chlorate and chlorine dioxide levels, which might enter an average POTW would be estimated as:

chlorite	$8.1 \text{ ppm} \times 13.2\% = 1069 \text{ ppb}$
chlorate	$\leq 0.5 \text{ ppm} \times 13.2\% = \leq 66 \text{ ppb}$
chlorine dioxide	$\leq 0.02 \text{ ppm} \times 13.2\% = \leq 2.6 \text{ ppb}$

While the above estimated worst case value for chlorite exceeds the LC50 for Mysid Shrimp (refer to Section 8.1 of the Environmental Assessment of this petition), the oxidative tendency of this oxychlorine species to be chemically reduced by organic matter in both the processed-products treatment waters, plant sanitation waters, and subsequent municipal water treatment facilities, means that the final level of this material is expected to be de minimus and to be of no impact to aquatic species. For sodium chlorate, the estimated levels expected to be generated from a typical ASC application system are significantly below the >1000 ppm LC50 of freshwater and marine fish for this oxychlorine species. Finally, the rapidity of degradation, of chlorine dioxide in organic environments, eliminates this oxychlorine species from any consideration regarding aquatic toxicity. In aggregate, entry of the above levels of oxychlorine species in a POTW is therefore not expected to pose any risk towards aquatic species.

Similarly, the maximum contribution of a food grade acid would be estimated as:

sulfuric acid	$\leq 0.45 \text{ ppm} \times 13.2\% = \leq 0.06 \text{ ppm}$
phosphoric acid	$1.8 \text{ ppm} \times 13.2\% = \leq 0.24 \text{ ppm}$
citric acid	$81.3 \text{ ppm} \times 13.2\% = 10.7 \text{ ppm}$

Alcide Corporation does not therefore believe that the above-indicated concentrations of oxychlorine species or food acids will have a negative impact on the operation of POTWs, for the following reasons:

- 1) Neither chlorite, chlorate nor chlorine dioxide is listed as an Interfering Substance in POTWs, as provided in Page 125 of the Wetzel document<sup>14</sup>. These interfering substances, as contained in certain industrial discharges, can cause "a POTW's noncompliance with its permit or inability to lawfully use or dispose of its sludge." Chloride was listed as a potentially interfering substance, but at a level significantly higher (180 ppm) than its presence either as an impurity in the technical grade chlorite or if all the oxychlorines were converted to chloride. Acidity is also listed as a potential interference in POTW operation, but the levels contributed by this application would not have a measurable impact on pH.
- 2) None of the species present at the levels indicated can interfere with the microbiological treatment systems. Chlorine dioxide, a recognized antimicrobial, will have no effect at the maximum ppb levels calculated; neither can the chlorite, a much weaker source of activity, at the 1069 ppb level calculated.
- 3) "Most interference problems at POTWs are related to intermittent discharges of high-strength conventional wastes which overload a POTW's organic capacity, causing plant upset," according to an EPA reporter<sup>15</sup>. The organic contribution of these systems is minimal, and the other common causes of plant interference are not a factor here:

low pH .....[corrosion]

solids or viscous pollutants.....[flow obstruction]  
high volatiles .....[explosion or fire hazard]  
heated discharges .....[altered biological activity]  
toxic discharges ..... [inhibited biological activity]

#### **6.2.2.e WATER RELEASES – SMALLER FACILITIES**

It is projected that most of the preparation of products, which are the subject of this petition, up to 70%, will be produced in the larger facilities. The remaining ASC usage will be distributed over a wide range of local facilities of low volume production, thereby reducing the “per site” ASC volume.

Because of the diversity of such small-use operations the prediction of specific ASC quantities with respect to other waters in the effluent of a particular type of facility is not feasible. However it can be readily concluded that the much smaller chlorite and acid quantities in the facility’s effluent would be at least as likely to react with and be degraded by the organic matter in its effluent water as in the larger facilities. Once again, the maximum level of oxychlorines (mostly chlorite) that might be expected in the plant effluent of a facility operation is ~ 9 ppm. The same basic calculations with respect to impact on POTWs apply.

#### **6.2.2.f AIR RELEASES – LARGER AND SMALLER FACILITIES**

As seen earlier, based on the plant data from ASC application to whole carcasses, the spray application of an ASC solution to the surfaces of further processed products creates negligible air levels of chlorine dioxide, in an environment of normal air turnover, assuming the use of an appropriately designed spray cabinet enclosure to confine its dispersal and to control the gaseous and liquid effluents.

In ASC immersion dip operations, small levels of chlorine dioxide may have formed in the solution upon its activation. As with the SANOVA<sup>®</sup> commercial spray systems, the environment surrounding an immersion or dipping operation will be controlled with appropriate enclosures, containment of liquid wastes and positive pressure air venting. In experiments in which processed products (hot dogs, cocktail franks) were immersed in ASC dip solutions, there was no noticeable odor of chlorine dioxide generated. The odor threshold for chlorine dioxide detection is ~0.1 ppm<sup>16</sup>. The OSHA TLV for chlorine dioxide is also 0.1 ppm, for continuous 8-hour exposure<sup>17</sup>.

### **6.2.3. RELATION OF PLANT WATER RELEASES TO TOTAL PUBLICLY OWNED TREATMENT WORKS QUANTITIES**

The industrial discharges to local POTWs, such as might be expected to occur from facilities for production of products which are the subject of this petition, are further diluted by discharges from other industrial and non-industrial sources. The previous section of this petition discussed the relationship of such plant discharges to total POTW intakes. Reference was made to an EPA-sponsored study<sup>15</sup> that provided guidance in minimizing the discharge effects on these POTWs. In this report it was shown that the average influent wastewater from industrial sources was 26.3% of the total intake. That information was used to estimate the projected impact of the processed products facilities using ASC treatments.

As calculated in Section 6.2.2.b, the contribution of chlorite from a processed products preparation facility to its handling POTW is a maximum 1069 ppb.

A similar analogy holds for the food-grade acids used for ASC activation, where the acid contribution to POTW facilities would be *de minimus*.

On the basis of these discussions, Alcide corporation does not believe that the above-indicated concentrations of oxychlorine species or food acids will have a negative impact on the operation of POTWs, for the following reasons:

- a) The levels of oxychlorines, *i.e.*, chlorite, chlorate, and chlorine dioxide, that would reach the POTWs, are at ppb levels, at most. Neither chlorite, chlorate nor chlorine dioxide is listed as an Interfering Substance in POTWs, as provided in a document listing interferences at POTWs<sup>15</sup>. These interfering substances, as contained in certain industrial discharges, can cause "a POTW's noncompliance with its permit or inability to lawfully use or dispose of its sludge." Acidity is

also listed as a potential interference in POTW operation, but the levels contributed by this application would not have a measurable impact on pH.

- b) None of the species present at the levels indicated can interfere with the microbiological treatment systems. Chlorine dioxide, a recognized antimicrobial, will have no effect at the calculated ppb level; neither will the chlorite, a much weaker source of activity, at the minuscule levels possibly present.

#### **6.2.4 COMPLIANCE WITH EMISSION REQUIREMENTS**

Alcide Corporation fully anticipates that any processed products operation that intends to use the ASC solutions, if deemed appropriate, will obtain the necessary permits and approvals for discharging process waters containing chlorite, chlorate and chlorine dioxide to POTWs. It should be noted that sodium chlorite, used in preparation of these ASC solutions, is an EPA-registered product. It is Alcide Corporation's current intention to use one of three EPA registered sodium chlorite products for the proposed application (or the equivalent): Vulcan Chemicals 79% Technical Sodium Chlorite, Technical Sodium Chlorite Solution 31.25, or 31% Active Sodium Chlorite Solution. Copies of the Technical Data Sheets and Material Safety Data Sheets for these products are provided in Appendix 2 of this section. Alcide Corporation intends to request that Vulcan Chemicals include label copy which mandates that users of the sodium chlorite must discharge the solutions in accordance with the requirements of the facility's National Pollution Discharge Elimination System permit. Any warning statements on the labels concerning the hazard of the products to organisms that may be exposed to it in the environment will also be on the labels of the FDA-regulated use.

## 6.2.5. COMPLIANCE STATUS

Sodium chlorite has a number of commercial uses, primarily as a source of chlorine dioxide, *e.g.*, pulp and paper bleaching, drinking water treatment, as a slimeicide in cooling towers, as a food disinfectant, and as a cleaning agent in the electronics industry. The current U.S. usage of sodium chlorite is close to 25 million pounds (11.35 million Kg).

As shown in Section 6.2.1 of this petition, if all of the approximately 5,115 M lb of processed products which are within the scope of this petition processed in the U.S. per year were to be exposed to the maximum concentration of ASC treatment, the total sodium chlorite consumed would be 0.835 million Kg. On that basis a worst-case maximum consumption of sodium chlorite per year for this application could not be expected to exceed 7.3% of the total U.S. sodium chlorite market. However, Alcide Corporation's estimates of market share predict that the actual usage rates for sodium chlorite would be considerably less than this worst-case scenario. More realistically it can be postulated that actual use rates would not exceed 0.167 million Kg per annum or 1.5% of the sodium chlorite consumed annually in the US. Accordingly Alcide does not believe that approval for the proposed use will affect current compliance by sodium chlorite producers with environmental regulations.

Use of the food grade acid activators is significantly less, of a larger total commercial utilization, and a similar conclusion is drawn for these materials as well.

To the best of Alcide Corporation's knowledge and belief, there are no extraordinary circumstances pertaining to the manufacture of the substances (sodium chlorite and food grade organic acids) used in the creation of acidified sodium chlorite.

## 7.0 FATE OF EMITTED SUBSTANCES IN THE ENVIRONMENT

### 7.1 Introduction

Chlorine dioxide (produced from sodium chlorite) is used widely in drinking water treatment in the U.S. When chlorine dioxide reacts in drinking water, approximately 50 - 70% is converted back into chlorite and the remainder into chloride and chlorate. The MCL (Maximum Contaminant Level) for chlorite in drinking water is 1.0 ppm, corresponding to 1.34 ppm sodium chlorite. The Rfd (reference dose) for the chlorate ion is much higher than that for chlorite, and therefore the US EPA (Environmental Protection Agency) has not set a MCL for the chlorate ion. Under The Emergency Planning and Community Right-to-Know Act statute (40 CFR Sect. 313 TRI), the US EPA considers chlorine dioxide releases to the environment at levels below 1.0 ppm to be *de minimis*. Because chlorine dioxide decays rapidly into chlorite, chloride and chlorate, this limit is reflective of the low environmental toxicity of those ions as well.

The chlorite ion is thermodynamically unstable with respect to other chlorine species, e.g., hypochlorite and chloride. It reacts rapidly with Fe(II) and Mn(II) as well as with reduced sulfur species and organic compounds. It is also rapidly degraded photochemically. Consequently, it does not persist in the environment.

In the following, some of the aqueous reactions of the chlorite ion are examined along with its photochemical degradation.

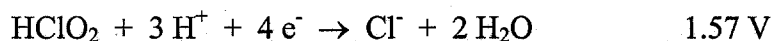


## 7.2 Chemical Degradation of Chlorite

In acid media, the chlorite ion is in equilibrium with chlorous acid

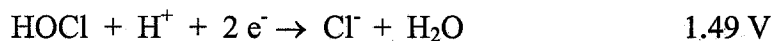


Below a pH of ~3.5 the following mechanisms predominate



The positive oxidation potentials indicate that the reactions proceed spontaneously as written.

The hypochlorous acid, HClO, produced from the second reaction rapidly reacts to produce chloride ion as shown in the following pathway:



This reaction is much faster than that of hypochlorous acid with organics. Consequently, very few chlorinated organics are formed.

At higher pH values, chlorite can degrade by one or both of the following pathways:



Chlorite can also undergo disproportionation reactions (reactions in which two or more molecules of one species react to produce one species with a higher oxidation state along

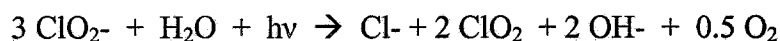
with one of lower oxidation state). This is illustrated in the following reaction in which chlorite/chlorous acid (oxidation state +3) decays into hypochlorous acid (oxidation state +1) and chlorate (oxidation state +5):



Fabian<sup>18</sup> demonstrated that iron(III) catalyzes the decomposition of chlorite. Iatrou *et al.*<sup>19</sup> investigated the feasibility of using ferrous iron (Fe(II)) to reduce chlorite concentrations. Laboratory tests indicated a required reaction stoichiometry of 3.0 - 3.1 mg Fe(II)/mg  $\text{ClO}_2^-$ . The reaction rate was rapid for pH values of 5 and greater. Interference from dissolved oxygen was minimal. The ferric hydroxide solids produced as a by-product for the Fe(II)- $\text{ClO}_2^-$  reaction had no adverse effect on alum coagulation for the removal of turbidity and dissolved organic carbon. Iron catalysis of chlorite is an important degradation pathway in both soils and wastewater streams.

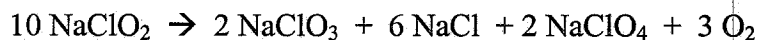
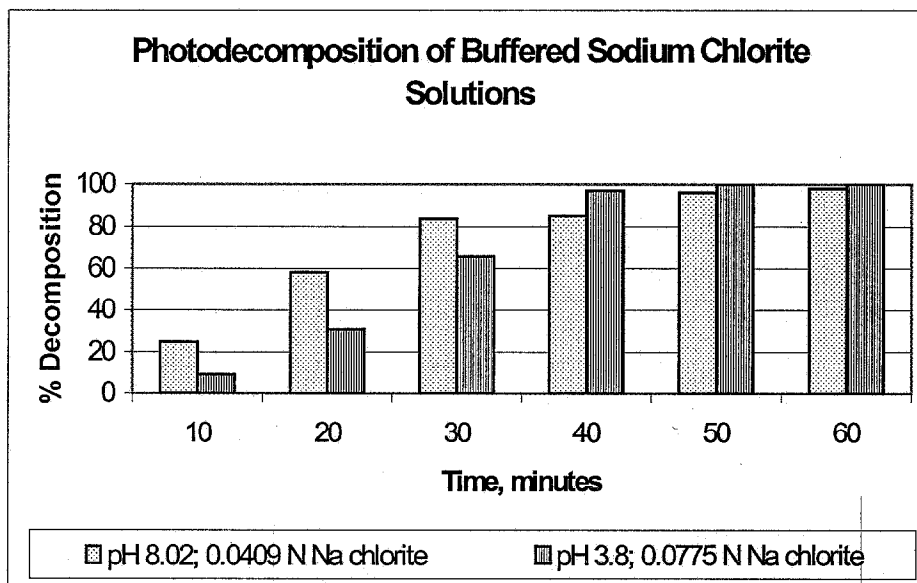
### 7.3 Photochemical Degradation of the Chlorite Ion

Buxton and Subhani<sup>20</sup> indicated that the chlorite ion undergoes photolytic decomposition to form chlorate, hypochlorite, chlorine dioxide and oxygen. The results of work by Cosson *et al.*<sup>21</sup> suggest that chlorate is not formed by direct photodecomposition of chlorite, but rather by decomposition of chlorine dioxide. Their results are consistent with the stoichiometry



Unless the chlorine dioxide formed from the photolysis of sodium chlorite solutions is removed from solution as soon as it is formed (e.g., via an air sparge) it is rapidly degraded into chlorate and chloride.

In 1964, Nabar *et al.*<sup>22</sup> published the results of their work on the photodecomposition of chlorite. The following figure shows their results for the fadeometer decomposition of a 0.0409 N NaClO<sub>2</sub> solution (3699 ppm) buffered at pH 8.2 and a 0.0775 N NaClO<sub>2</sub> solution (7009 ppm) buffered at pH 3.8. The half-life of the higher pH solution was less than 20 minutes; that of the pH 3.8 solution was less than 30 minutes. Decomposition of chlorite solutions by sunlight was reported to be significantly faster. Nabar *et al.* suggested the following photochemical reaction pathways for the degradation of chlorite under alkaline and acidic conditions, respectively:



In other work, Zika *et al.*<sup>23</sup> found that chlorite has a half-life of less than 10 minutes in direct sunlight. More recently, Wang<sup>24</sup> determined that chlorite solutions degraded rapidly (half-life ~ hours) under laboratory fluorescent lighting and even more rapidly in direct sunlight (half-

life ~ minutes). This was verified in a field trial at the Los Angeles Country Reservoir<sup>25</sup> in which chlorine dioxide was applied to control algal blooms. Chlorine dioxide was applied at night to give adequate reaction time with the algae present. Within four hours after sunrise, levels of both chlorine dioxide and its primary degradation byproduct, chlorite, were below detection limits.

#### 7.4 Chlorite Degradation in Soil

In 1999, Certified Laboratories (Plainview, NY) conducted a study (Appendix 3) to simulate the rate of degradation of a spilled chlorite-containing product (Alcide 4XLA Teat Dip, 2400 ppm chlorite acidified with lactic acid to a pH of 3.0). Three different soil samples differing in moisture and organic content were used. The results are shown in the following table. It was assumed that in a spill the product would be diluted 1:10. The last column gives the time at which the chlorite level was below the analytical detection limit (~20 ppm in the soils studied).

The rate of degradation was clearly a function of organic loading and also of soil moisture. From these samples, chlorite is not expected to be persistent in soils, and consequently will not have an adverse impact on the environment.

<b>Table 1. Chlorite Degradation in Soil</b>				
Characteristics of Soil Samples				
Sample	Moisture, %	Organics Dry Basis	Organics Soil Basis	Chlorite to "0.0"
A	30.0	13.34	9.34	4 hours
C	3.2	0.72	0.9	8 days
E	44.2	53.07	29.6	8 hours

## 7.5 Chlorite Degradation in Manure

In another study (Appendix 4), acidified sodium chlorite was added to cow manure at an initial level of 229 ppm. Aliquots were analyzed over a two-day period. The results, in Table 2, show that the chlorite levels had declined approximately 91% (to the 20 ppm detection limit of the method) within 24 hours.

Table 2. Chlorite Degradation in Manure	
Exposure time (hours)	[Sodium Chlorite] ppm
0	229
0.33	217
0.75	213
1.25	45
4.0	45
5.0	49
15	45
24	20
48	20
Note: Method detection limit was ~20 ppm.	

## 7.6 Chlorite Degradation in Poultry Processing Waste Waters

Recently, a study was conducted to evaluate the persistence of sodium chlorite in typical poultry processing wastewaters (Appendix 5). Samples of wastewater containing spent ASC (acidified sodium chlorite) treatment solution were collected from four poultry processing plants immediately prior to discharge to the local POTW (publicly owned treatment works), cooled, and shipped to a third-party laboratory for chlorite analysis. Samples were protected from UV exposure during the analytical process.

The following table gives specifics for the four plants where these samples were taken, as well as the calculated chlorite levels in the wastewater. The ASC solution as applied is 1000 ppm sodium chlorite. Typically, 90% of the applied solution goes to drain. The chlorite in this spent solution typically measures 900 ppm.

<b>Table 3. NaClO<sub>2</sub> Concentrations in 4 Poultry Processing Facilities Using ASC</b>					
Plant	Processing Rate Birds/Day	ASC Usage oz/bird	ASC Usage GPD	Total Plant Wastewater MGD	Calculated <sup>†</sup> [NaClO <sub>2</sub> ] ppm
1	232,050	6 oz	10,877	1.5	5.9
2	156,500	6 oz	7,336	1.5	3.96
3	154,833	6 oz	7,258	1.3	7.64
4	170,260	6 oz	7,981	1.2	5.39
<sup>†</sup> Calculated chlorite in plant effluent = ASC Usage ( 90% ( 900 ppm/Total Plant Wastewater					

When the samples were analyzed (Ion Chromatography, EPA Method 300.1), both chlorite and chlorate were not detected, indicating that chlorite is not persistent in the environment.

Furthermore, before discharge into the environment these wastewaters are commingled with other industrial wastewater discharges and domestic wastewaters. Assuming a typical POTW processes 25 MGD, any chlorite from the plants is diluted by a factor of 15-20 (25/1.5 to 25/1.2) using the examples above. The resulting calculated concentration of chlorite contribution to the total effluent entering POTW waters would be well below the 1.0 ppm MCL for drinking water, albeit no degradation occurs.

## 7.7. Conclusion

Theory predicts, and lab studies and analyses of actual samples (soil, manure, wastewater) confirm, that chlorite decays rapidly in the environment and is not expected to exert any adverse impact.

## 8.0 ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES

### 8.1 EFFECTS ON AQUATIC ORGANISMS

Summaries of relevant portions of this section, as presented in FAP 4A4433 for the oxychlorines that might enter the environment as a result of poultry meat carcass treatment are provided in the next paragraphs. Following the discussion of each specific oxychlorine is a projection of the effects from each of these materials as a result of the treatment of products which are the subject of this petition.

Sodium Chlorite: The LC<sub>50</sub> aquatic toxicity to fish and oyster species ranged from 41 to 149 ppm, and from 0.151 to 0.650 ppm for *Daphnia magna* and Mysid shrimp, resp. The US-EPA has determined that sodium chlorite is toxic to fish, on the basis of the *Daphnia magna* figure. It was shown in Section 6.2.2.b. that a theoretical maximum level of about 1069 ppb of sodium chlorite would reach the typical POTW. During subsequent wastewater treatment or at the POTW, chlorite will mix with other organic laden waters and be rapidly reduced. For effluents that might not be directed to POTWs, but are directed to catch ponds and leaching beds, the high levels of organic matter in the earth environment would rapidly reduce the chlorite to safe levels before the entraining water reached habitable waters for aquatic species.

Sodium Chlorate: The LC<sub>50</sub> for freshwater and marine fish is consistently >1000 ppm. Sodium chlorate, being a small fraction of the impurities in technical grade sodium chlorite, and forming to only a minor extent during the degradation of ASC solutions, is therefore of no concern from their use in carcass treatments. This conclusion is also directly applicable to the lower volume use of ASC for treatment of products which are the subject of this petition.

Chlorine Dioxide: The rapidity of degradation of chlorine dioxide in organic environments, coupled with its minimum production in ASC solutions eliminates any aquatic toxicity concerns from carcass treatments. This conclusion is also appropriate for effluents resulting from ASC use on products which are the subject of this petition.

## 8.2. EFFECTS ON TERRESTRIAL ORGANISMS

A summary of the corresponding section in the prior FAP, 4A4433, for poultry carcass processing, is provided in the following paragraphs.

A broad variety of toxicological studies have been carried out on the oxychlorine species chlorite, chlorate and chlorine dioxide, in connection with the worldwide use of chlorine dioxide in the disinfection of potable water. The  $\text{ClO}_2$  has been found to produce virtually no chlorinated hydrocarbons as potential mutagens, as does chlorine. On a concentrated basis, the oxychlorines have been found to cause oxidative changes to erythrocytes, both in loss of structural integrity and formation of methemoglobin. However at the ppb levels where these materials may be found in red meat processing plant effluents, be they primary or sub primal and secondary meat grinding operations, the data obtained in connection with drinking water levels of the oxychlorines are more relevant.

On an acute basis, the toxicity of sodium chlorite is in the range of 300 - 350 mg/Kg, based on the  $\text{LD}_{50}$  values for mice, rats, and guinea pigs. For sodium chlorate, the  $\text{LD}_{50}$ s cover the range of ~600 to 8000 mg/Kg for mice, rats, dogs, cats and rabbits. With respect to the acute toxicity of chlorine dioxide, an  $\text{LD}_{\text{LO}}$  of 500 ppm was found for 15 minutes air exposure by rats. In man, a 5-ppm level in the air was found to be an irritant to the respiratory and G.I. tracts. Such levels would not be found in meat processing plants, either carcass, grinding, or processed products operations, where any sub-ppm levels of  $\text{ClO}_2$  formed during production of the ASC solutions would be rapidly destroyed by organic matter on the products.



A variety of sub-acute studies have been conducted on animals and human volunteers, who ingested waters containing up to 40 ppm of chlorine dioxide in a single episode, or 5 ppm solutions of chlorine dioxide or sodium chlorite for a 12 week period. In the latter case there were some effects on blood chemistry, but little other effects. In the former case there was headache, nausea and abdominal discomfort which passed in 5 minutes.

U.S. EPA's recently completed re-assessment of chlorite and chlorine dioxide safety has established a Reference Dose (RfD) for both of these materials of 0.03/mg/kg/day in drinking water, based on an NOAEL (No Observable Adverse Effect Level) of 3 mg/kg/day and a 100-fold safety factor<sup>26</sup>. This corresponds to 2.1 mg/kg/day intake of chlorite or chlorine dioxide for a 70 kg individual. The report of the American Water Works Association's evaluation of chlorite and chlorate residues established a NOEL for chlorate of 78 mg/kg/day, which translates to a maximum intake of 54.6 mg of chlorate per day for a 70 kg person, including the 100 fold safety factor<sup>27</sup>.

On the basis of the oxidative tendency of these oxychlorine species to be chemically reduced by organic matter in both the processed-products treatment, plant sanitation waters, and subsequent municipal water treatment facilities, the levels of the three oxychlorine species are anticipated to be significantly lower in waste waters than are the actual levels calculated to be of minimal risk to individuals.

### 8.3 ENVIRONMENTAL BENEFITS

The use of acidified sodium chlorite acid systems for treatment of products which are the subject of this petition offers the possibility of several environmental benefits:

#### 8.3.1 NON-FORMATION OF MUTAGENS AND CARCINOGENS

In those instances where ASC solutions might be used, or are used in place of chlorinated water for disinfecting product surfaces (not a common practice), the potential for the formation of chlorinated organic materials in the environment would be significantly reduced.

#### 8.3.2. REDUCTION IN AQUATIC TOXICITY

Similar considerations would apply to the reduction of hypochlorite in aquatic environments, which has the following toxicity<sup>28</sup>

- Cold water fish: 0.132 – 135 ppm (LC<sub>50</sub>-96 hr)
- Warm water fish: 0.28 - 2.1 ppm (LC<sub>50</sub>-96 hr)
- *Daphnia magna*: 0.037 - 2.1 ppm (LC<sub>50</sub>-48 hr)

These data indicate that chlorine/hypochlorite is much more toxic to both cold and warm freshwater fish than is chlorite or chlorate, and generally slightly more toxic to the *Daphnia magna* invertebrate.

Chlorine Dioxide: The rapidity of degradation of chlorine dioxide in organic environments, coupled with its minimum production in ASC solutions eliminates any

aquatic toxicity concerns from carcass treatments. This conclusion is also appropriate for effluents resulting from ASC use on meat cuts prior to their comminution.

## 9.0 USE OF RESOURCES AND ENERGY

As shown earlier in Section 6, in the worse case scenario, if all of the products which are the subject of this petition prepared in the U.S. were to be treated with ASC solution, the amount of additional sodium chlorite consumed would be 7.3% of the total present consumption of sodium chlorite. Inasmuch as the eventual use of ASC solutions in these multiple applications will obviously be significantly less than that maximum (estimated to be around 1.5%), the impact on national resources and energy by such incremental use will be of minimal significance. Also no minerals will be used in the preparation or production of the subject additive. Environmental releases of chlorite, chlorate, chlorine dioxide and any of the GRAS acid activators are not expected to adversely affect threatened or endangered species nor impact historic structures.

## 10.0 MITIGATION MEASURES

No adverse environmental effects are anticipated from residual "worst-case" levels of chlorine dioxide as a result of any aspect of use of the subject additive, if this petition is approved. Therefore, no mitigation measures are required.

## 11.0 ALTERNATIVES TO PROPOSED ACTION

Inasmuch as no potential adverse environmental effects are expected to occur, no mitigation alternative actions are necessary.

## 12.0 PREPARERS

This Environmental Assessment was prepared by G. Kere Kemp, Chief Scientific Officer, and Cecilia M. Morse, Senior Associate, Regulatory Affairs, Alcide Corporation. Dr. Kemp has an educational background in Veterinary Science. His 25 years of work experience have been primarily directed toward the fields of microbiology, pharmacology and pharmacotherapeutics with specific focus on the development and registration of novel and unique antimicrobial substances for potential uses in animal, human and industrial applications. Ms. Morse has an educational background in analytical chemistry. Her 15 years of work experience have been primarily directed toward quality control, quality assurance and regulatory affairs of pharmaceutical products.

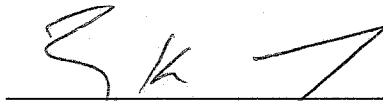
## 13.0 CERTIFICATION

The undersigned official certifies that the information presented is true, accurate and complete to the best knowledge of the firm.

Date:

January 31, 2007

Signature:



Name:

G. Kere Kemp

Title:

Executive Vice President

Chief Scientific Officer



## 14.0 APPENDICES

- Appendix 1. Carlisle Consulting. *Air Sampling Surveys for Chlorine and Chlorine Dioxide Around SANOVA® Installations in Commercial Poultry Plants*. 1999, Carlisle Consulting, Harrison, Arkansas.
- Appendix 2. Sodium Chlorite Technical Data Sheets and Materials Safety Data Sheets.
- Appendix 3. Soria, Y., *Degradation of Chlorite in Soil*. 1999, Certified Laboratories, Inc.: Plainview, NY. p. 81.
- Appendix 4. Certified Laboratories, Inc., *Degradation of Chlorite in Cow Manure*. 1999, Certified Laboratories, Inc.: Plainview, NY. p. 23.
- Appendix 5. ABC Research Laboratories, *Determination of Chlorite, Chloride, and Chlorate in Waste Stream Waters*. 2000, ABC Research Laboratories: Gainesville, Florida.

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